

General

Guideline Title

Clinical practice guidelines on the use of integrative therapies as supportive care in patients treated for breast cancer.

Bibliographic Source(s)

Greenlee H, Balneaves LG, Carlson LE, Cohen M, Deng G, Hershman D, Mumber M, Perlmutter J, Seely D, Sen A, Zick SM, Tripathy D, Society for Integrative Oncology Guidelines Working Group. Clinical practice guidelines on the use of integrative therapies as supportive care in patients treated for breast cancer. J Natl Cancer Inst Monographs. 2014 Nov;2014(50):346-58. [174 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The grading for the strength of recommendations (A-D, H-I) and level of certainty of recommendations (high, moderate, low) are provided at the end of the "Major Recommendations" field.

Note: There were a large number of therapies that were deemed to have insufficient evidence to form recommendations. Supplementary Tables 2-13, available online (see the "Availability of Companion Documents" field), include references and information regarding such therapies. A small number of natural products that were investigated in large and/or multiple trials and did not have an effect were given a Grade D.

Anxiety and Stress

Music therapy [Grade B (Binns-Turner et al., 2011; Hanser et al., 2006; Bulfone et al., 2009; Li et al., 2012)] is recommended for the short term relief of anxiety during radiation therapy and chemotherapy. Meditation [Grade B (Crane-Okada et al., 2012; Kim et al., 2013; Lengacher et al., 2009; Würtzen et al., 2013)] including mindfulness-based stress reduction, yoga [Grade B (Banerjee B et al., 2007; Bower et al., 2012; Chandwani et al., 2010; Dhruva et al., 2012; Pruthi et al., 2012; Raghavendra et al., 2007; Rao et al., 2009; Vadiraja et al., "Effect of a yoga program on cortisol rhythm," 2009)], and stress management programs [Grade B (Aguado Loi et al., 2012; Garssen et al., 2013; Carlson et al., 2013; Jacobsen et al., 2013; Phillips et al., 2008)] are recommended to reduce longer term anxiety both during and after treatment. Longer stress management groups (Phillips et al., 2008) are likely more effective than short home study programs (Aguado Loi et al., 2012). Acupuncture [Grade C (Molassiotis et al., 2012)] can be considered for treating anxiety concurrent with ongoing fatigue. Relaxation [Grade C (Hidderley & Holt, 2004; KovaĀiĀ & KovaĀiĀ, 2011; Molassiotis et al., 2002; Nunes et al., 2007; KovaĀiĀ, ZagoriĀnik, & KovaĀiĀ, 2013)] and massage therapy [Grade C (Billhult, Bergbom, & Stener-Victorin, 2007; Hernandez-Reif et al., 2004; Listing et al., 2010; Wilkinson et al., 2007)] both can be considered for the short-term relief of anxiety during treatment. In this section, outcomes of "pure" anxiety and stress were considered [e.g.,

State-Trait Anxiety Inventory (Spielberger, 1983) and Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983)]. Mixed measures of general mood [e.g., Profile of Mood States (McNair, Lorr, & Droppleman, 1992)] were grouped in the next section with traditional depression outcomes [e.g., Beck Depression Inventory (Beck & Beamesderfer, 1974)]. For the purposes of these guidelines, mindfulness-based stress reduction is considered to be a form of meditation. The primary emphasis of mindfulness-based stress reduction is on daily training in traditional contemplative mindfulness meditation practices including sitting, lying, and walking meditation with mindful movement using gentle Hatha yoga poses. For further details, see Supplementary Table 2 in the Data Supplement.

Depression and Mood

Meditation [Grade A (Crane-Okada et al., 2012; Kim et al., 2013; Lengacher et al., 2009; Würtzen et al., 2013; Carlson et al., 2013; Henderson et al., 2013; Hoffman et al., 2012; Milbury et al., 2013; Nidich et al., 2009)] particularly mindfulness based stress reduction, is recommended for improving mood and depression during radiation therapy and post treatment. Yoga alone [Grade A (Banerjee et al., 2007; Bower et al., 2012; Chandwani et al., 2010; Dhruva et al., 2012; Pruthi et al., 2012; Raghavendra et al., 2007; Vadiraja et al., "Effects of a yoga program on cortisol rhythm," 2009; Culos-Reed et al., 2006; Danhauer et al., 2009; Moadel et al., 2007; Vadiraja et al., "Effects of yoga program on quality of life," 2009)] and relaxation [Grade A (Hilderley & Holt, 2004; Molassiotis et al., 2002; Nunes et al., 2007; Yoo et al., 2005; Walker et al., 1999)] are also recommended for improving mood and depressive symptoms during radiation therapy and chemotherapy and in the presence of fatigue. For newly diagnosed patients, music therapy [Grade B (Hanser et al., 2006; Burns, 2001; Zhou et al., 2011)] is recommended to improve mood and depressive symptoms. Massage [Grade B (Hernandez-Reif et al., 2004; Listing et al., 2010; Wilkinson et al., 2007; Krohn et al., 2011; Listing et al., 2009; Fernández-Lao et al., "Attitudes toward massage," 2012)] is recommended for improving mood disturbance in post treatment survivors. Stress management [Grade C (Aguado Loi et al., 2012; Garssen et al., 2013; Jacobsen et al., 2013)] can be considered to improve mood and depressive symptoms. Healing touch [Grade C (Post-White et al., 2003; Jain et al., 2012)] can be considered for improving mood in patients undergoing chemotherapy. Acupuncture [Grade C (Molassiotis et al., 2012; Walker et al., 2010)] can be considered for improving depressive symptoms in women suffering from hot flashes. For further details, see Supplementary Table 3 in the Data Supplement.

Fatigue

Energy conservation/activity management [Grade B (Barsevick et al., 2004)] is recommended for fatigue management. Qigong [Grade C (Chen et al., 2013; Oh et al., 2010)] and post treatment acupuncture [Grade C (Molassiotis et al., 2012; Johnston et al., 2011; Deng et al., 2013; Smith et al., 2013)] can also be considered to manage fatigue. About 2000 mg daily of encapsulated American ginseng root powder standardized to 3% ginsenosides [Grade C (Barton et al., 2013; Barton et al., 2010)] can be considered to improve fatigue during chemotherapy and radiation. An estrogenic effect from a ginseng methanolic extract has been observed in breast cancer cell lines (King, Adler, & Murphy, 2006; Gray et al., 2004; Liu et al., 2001; Duda et al., 1999). However, the formulation studied in the trials was a whole root product for which no long-term evidence exists regarding safety or harm. Acetyl-L-carnitine [Grade D (Hershman et al., 2013)] and guarana [Grade D (da Costa Miranda et al., 2009; de Oliveira Campos et al., 2011)] are not recommended for the treatment of fatigue due to lack of effect. For further details, see Supplementary Table 4 in the Data Supplement.

Sleep Quality

Gentle yoga [Grade C (Bower et al., 2012; Chandwani et al., 2010; Danhauer et al., 2009; Mustian et al., 2013)] and stress management techniques [Grade C (Garssen et al., 2013; Andersen et al., 2013)] can be considered for treatment of sleep disruption. For further details, see Supplementary Table 5 in the Data Supplement.

Global Quality of Life and Physical Functioning

Meditation [Grade A (Crane-Okada et al., 2012; Kim et al., 2013; Lengacher et al., 2009; Henderson et al., 2013; Hoffman et al., 2012; Nidich et al., 2009; Henderson et al., 2012)] is recommended for improving quality of life, while relaxation and guided imagery [Grade C (Yoo et al., 2005; Walker et al., 1999; Burns, 2001; Richardson et al., 1997)], qigong [Grade C (Chen et al., 2013; Oh et al., 2012)], reflexology [Grade C (Dyer et al., 2013; Sharp et al., 2010; Wyatt et al., 2012)], stress management [Grade C (Aguado et al., 2012; Garssen et al., 2013; Jacobsen et al., 2013; Antoni et al., 2006; Lerman et al., 2012)], and yoga [Grade C (Chandwani et al., 2010; Dhruva et al., 2012; Pruthi et al., 2012; Raghavendra et al., 2007; Culos-Reed et al., 2006; Danhauer et al., 2009; Moadel et al., 2007; Vadiraja et al., "Effects of yoga program on quality of life," 2009; Banasik et al., 2011; Littman et al., 2012)] can also be considered. Acupuncture studies [Grade C (Molassiotis et al., 2012; Frisk et al., 2012; Molassiotis et al., 2013)] demonstrated mixed results for improving quality of life, although no studies showed deleterious effect. Mistletoe [Grade C (Semiglazov et al., 2006; Semiglazov et al., 2004; Tröger et al., 2009)] can be considered for improving quality of life in the short term, but there are limited data assessing long-term effects, interactions, and toxicities. There is some evidence of reversible hepatotoxicity at high doses of mistletoe (Schöffski et al., 2005; Schöffski et al., 2004). Exercise programs that include a relaxation/stress management component [Grade C (Jacobsen et al., 2013; Adamsen et al., 2009)] can be considered as options for improving physical functioning, while programs oriented towards energy conservation [Grade D (Barsevick et al., 2004; Barsevick et al., 2010)] are not recommended. For further details, see

Supplementary Table 6 in the Data Supplement.

Chemotherapy-Induced Nausea and Vomiting (CINV)

Electroacupuncture [Grade B (Beith et al., 2012; Shen et al., 2000)], acupressure [Grade B (Dibble et al., 2000; Dibble et al., 2007; Molassiotis et al., 2007)], and progressive muscle relaxation [Grade C (Molassiotis et al., 2002; Yoo et al., 2005)] can be considered as an addition to antiemetics for controlling CINV. There is stronger evidence on the use of acupuncture/electroacupuncture for CINV in other cancer populations (Ezzo, Streitberger, & Schneider, 2006; Ezzo et al., 2005; Garcia et al., 2013; NIH Consensus Conference, 1998). Ginger [Grade C (Panahi et al., 2012; Ryan et al., 2012)] in combination with antiemetics can be considered to control acute nausea, but not acute vomiting nor delayed nausea and vomiting. There is similar evidence on the use of ginger to control nausea in other populations (Marx et al., 2013; Lee & Oh, 2013). However, ginger should not be co-administered with the antiemetic aprepitant because of a possible negative interaction between the two agents on delayed CINV (Zick et al., 2009). Glutamine [Grade D (Bozzetti et al., 1997; Peterson, Jones, & Petit, 2007)] is not recommended for treatment of CINV due to lack of effect. For further details, see Supplementary Table 7 in the Data Supplement.

Pain

Healing touch [Grade C (Post-White et al., 2003)] and energy and sleep enhancement programs [Grade C (Barsevick et al., 2010)] can be considered for treating pain during chemotherapy. Music therapy [Grade C (Binns-Turner et al., 2011; Li et al., 2011)], a physical training program that includes a mind–body modality [Grade C (Cantarero-Villanueva et al., 2012; Fernández-Lao et al., "Effectiveness of multidimensional physical therapy," 2012)] and hypnosis [Grade C (Montgomery et al., 2007; Montgomery et al., 2002)] can be considered for treating pain associated with cancer surgery. Acupuncture [Grade C (Bao et al., 2013; Crew et al., 2007; Crew et al., 2010)] and electroacupuncture [Grade C (Oh et al., 2013; Mao et al., 2014)] can be considered for pain associated with aromatase inhibitor-associated musculoskeletal symptoms. For further details, see Supplementary Table 8 in the Data Supplement.

Taxane-Induced Neuropathy

Acetyl-L-carnitine is not recommended for prevention of taxane-induced neuropathy and was shown to increase neuropathy in one large study [Grade H (Hershman et al., 2013)]. For further details, see Supplementary Table 9 in the Data Supplement.

Lymphedema

Manual lymph drainage [Grade C (Andersen et al., 2000; Devoogdt et al., 2011; Dayes et al., 2013; Gurdal et al., 2012; Maher et al., 2012; McNeely et al., 2004; Williams et al., 2002)] and low-frequency laser therapy [Grade C (Ahmed Omar, Abd-El-Gayed Ebid, & El Morsy, 2011; Ridner et al., 2013)] can be considered for reducing arm volume and improving lymphedema-related quality of life, particularly among those breast cancer survivors who are unable to tolerate compression bandaging due to allergies or discomfort. For further details, see Supplementary Table 10 in the Data Supplement.

Vasomotor Symptoms

Acupuncture [Grade C (Walker et al., 2010; Bao et al., 2014; Bokmand & Flyger, 2013; Deng et al., 2007; Hervik & Mjåland, 2010; Liljegren et al., 2012)] and electroacupuncture [Grade C (Nedstrand et al., 2005; Frisk et al., 2008)] can be considered for reducing hot flashes in survivors. At the dose and formulations tested, soy isoflavone extracts or soy as food [Grade D (MacGregor et al., 2005; Quella et al., 2000; Van Patten et al., 2002)] cannot be recommended to prevent or treat hot flashes in breast cancer survivors because it has not been found to be efficacious. For further details, see Supplementary Table 11 in the Data Supplement.

Acute Skin Reaction From Radiation Therapy

Aloe vera gel [Grade D (Heggie et al., 2002; Williams et al., 1996)] and hyaluronic acid [Grade D (Kirova et al., 2011; Pinnix et al., 2012)] are not recommended to prevent or treat acute radiation skin reaction from radiation therapy due to lack of effect. For further details, see Supplementary Table 12 in the Data Supplement.

Other Outcomes

There are insufficient data from existing trials to make guideline-level recommendations on interventions to prevent and/or treat side effects and symptoms related to cognition, anemia, neutropenia/leukopenia, alopecia, cardiomyopathy and adherence to standard treatment. The search did not identify any eligible trials that addressed hepatic, renal, or gynecologic toxicities or side effects. For further details, see Supplementary Table 13 in the Data Supplement.

Definitions

Society for Integrative Oncology Grade of Recommendations*

Grade	Definition	Suggestion for Practice
A	Recommends the modality. There is high certainty that the net benefit is substantial.	Offer/provide this modality.
B	Recommends the modality. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this modality.
C	Recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this modality for selected patients depending on individual circumstances.
D	Recommends against the service. There is moderate or high certainty that the modality has no net benefit.	Discourage the use of this modality.
H	Recommends against the service. There is moderate or high certainty that the harms outweigh the benefits.	Discourage the use of this modality.
I Statement	Concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Society for Integrative Oncology Level of Certainty of Recommendations*

Level of Certainty**	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative breast cancer patient populations. These studies assess the effects of the modality and conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the modality on health outcomes, but confidence in the estimate is constrained by such factors as: the number, size, or quality of individual studies; inconsistency of findings across individual studies; limited generalizability of findings to routine breast oncology practice; and lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: the limited number or size of studies; important flaws in study design or methods; inconsistency of findings across individual studies; gaps in the chain of evidence; findings that are not generalizable to routine breast oncology practice; and a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

*Recommendation grading adapted from U.S. Preventive Services Task Force

**Certainty is defined as "likelihood that the Society for Integrative Oncology Guidelines Working Group assessment of the net benefit of a supportive care service is correct." The net benefit is defined as benefit minus harm of the supportive care service as implemented in a general breast oncology population. The Society for Integrative Oncology Guidelines Working Group assigns a certainty level on the basis of the nature of the overall evidence available to assess the net benefit of a supportive care service.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Symptoms and side effects encountered during breast cancer treatment

Guideline Category

Management

Prevention

Treatment

Clinical Specialty

Internal Medicine

Nursing

Obstetrics and Gynecology

Oncology

Physical Medicine and Rehabilitation

Psychology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Occupational Therapists

Patients

Physical Therapists

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Social Workers

Guideline Objective(s)

To inform clinicians, patients, and researchers of the state-of-the-science regarding the evidence-based use of complementary and integrative therapies for patients receiving breast cancer treatment

Target Population

Breast cancer patients during treatment, including surgery, chemotherapy, hormonal/biological therapy, and radiation therapy

Interventions and Practices Considered

1. Music therapy
2. Meditation
3. Stress management

4. Yoga
5. Acupuncture/acupressure/electroacupuncture
6. Massage
7. Relaxation/progressive muscle relaxation
8. Healing touch
9. Energy conservation
10. American ginseng
11. Modified qigong
12. Acetyl-L-carnitine (not recommended for treatment of fatigue or neuropathy)
13. Guarana (not recommended for treatment of fatigue)
14. Guided imagery
15. Mistletoe
16. Reflexology
17. Exercise/awareness
18. Ginger
19. Glutamine (not recommended for chemotherapy-induced nausea and vomiting [CINV])
20. Energy and sleep enhancement programs
21. Hypnosis
22. Physical training program that includes a mind-body modality
23. Low-frequency laser therapy
24. Manual lymphatic drainage
25. Soy (not recommended for treatment of hot flashes)
26. Aloe vera (not recommended for acute radiation skin reaction)
27. Hyaluronic acid cream (not recommended for acute radiation skin reaction)

Note: A large number of therapies were considered but were deemed to have insufficient evidence to form recommendations. Supplementary Tables 2-13, available online (see the "Availability of Companion Documents" field), include references and information regarding such therapies.

Major Outcomes Considered

- Fatigue
- Gastrointestinal outcomes (e.g., chemotherapy-induced nausea and vomiting [CINV])
- Gynecological outcomes
- Hematological outcomes
- Lymphedema
- Neurological outcomes
- Neuromuscular outcomes
- Pain
- Psychological outcomes (depression, anxiety, stress, mood)
- Quality of life and physical functioning
- Renal outcomes
- Skin reactions from radiation therapy
- Sleep quality
- Vasomotor symptoms

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Methodology for Search

The guidelines working group performed a systematic review of published randomized controlled trials assessing the safety and effectiveness of integrative modalities as supportive care in women receiving standard breast cancer treatment. The panel of experts compiled search keywords associated with the interventions and outcomes of interest (see Supplementary Appendix 1 in Data Supplement [see the "Availability of Companion Documents" field]). Nine databases (EMBASE, MEDLINE, PubMed, CINAHL, PsycINFO, Web of Science, SCOPUS, AMED, and Acutrial) were searched for studies published between January 1, 1990 and December 31, 2013.

The search yielded 4900 unique articles. Article titles and abstracts were initially screened by at least two reviewers for inclusion for full review. Articles were selected for inclusion in the systematic review if they met the following criteria: 1) randomized controlled trial; 2) available in English; 3) included at least 50% breast cancer patients and/or reported results separately for breast cancer patients; 4) used an integrative modality as an intervention during standard treatment with surgery, chemotherapy, radiation therapy, and/or hormonal therapy, or addressed long-term side effects resulting from diagnosis and/or treatment; and 5) had an outcome of interest. Other systematic reviews and meta-analyses were excluded. Full-text of all articles that met these criteria were assembled in an online database accessible to the working group (Mendeley database, www.mendeley.com). A second round of screening consisted of a full-text scan to further remove articles that did not meet the inclusion criteria.

Number of Source Documents

A total of 203 articles met the criteria for final inclusion in the review.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Delphi Method)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality Scoring

Quality was assessed using the Jadad scoring scale and a modified scale adapted from Delphi scoring scale. Quality scores were used to assess the strength of the recommendation. The Jadad scale is based primarily on three questions with addition/deduction allowed for deeper assessment of two of the three questions (see Supplemental Table 1 [see the "Availability of Companion Documents" field]). The scale is easy to use and widely accepted. Thus the total score can range between 0 and 5, with higher score indicating a better quality. A major criticism of the scale, however, is its overly generic assessment criteria that may not be relevant for all types of studies and its lack of assessment of the analytical quality of the study. The Delphi scale addresses this limitation by incorporating an assessment of statistical quality and further details on blinding. It is a nine item scale with every item scored on a 3-point scale (yes, no, don't know). The modified scale used for the guideline investigation dropped the item assessing equivalence of study arms at baseline from Delphi scale and added an item that addresses the power issue. Further, some of the response categories were redefined as a dichotomy. The total score of the modified scale ranges between 0 and 9 with high score indicating, as before, a study of superior quality. The complete scoring instrument is provided in Table 2 in Supplemental Appendix 2 (see the "Availability of Companion Documents" field).

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Quality Scoring Criteria

Data from the 203 articles were extracted and scored based on study quality. Two reviewers were assigned each article and discrepancies were addressed by a third reviewer. Quality was assessed using the Jadad scoring scale and a modified scale adapted from the Delphi scoring scale.

See the "Rating Scheme for the Strength of the Evidence" field and the Data Supplement (see the "Availability of Companion Documents" field) for additional details and evidence tables. Study quality was not an exclusion criterion, but was a measure of validity, which along with the magnitude and certainty of benefit or harm, guided the grading of clinical recommendations.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Selection of Expert Panel

A multidisciplinary panel of experts in oncology and integrative medicine was assembled to prepare these clinical practice guidelines. Panel members have expertise in medical oncology, radiation oncology, nursing, psychology, naturopathic medicine, traditional Chinese medicine, acupuncture, epidemiology, biostatistics, and patient advocacy.

Clinical Recommendations

For each modality applied to a specific outcome, a modified version of the US Preventive Services Task Force grading system was used to develop and grade recommendations (see the "Rating Scheme for the Strength of the Recommendations" field). If a trial had multiple outcomes, each outcome was assessed individually as it applied to the body of evidence for the specific modality/outcome pair. Ingestible and injectable natural products were specifically assessed for potential risk of toxicities and/or interactions with concurrent breast cancer therapies given the potential for drug interactions. The panel of experts compiled the data and drafted the recommendations.

Overview

The recommendations from the systematic review are based on the strength of evidence using accepted standards. Along with trial quality and size, the panel considered the magnitude and type of benefit as well as harms to formulate practical, responsible, and defensible guidelines. Most of the guidelines are focused on the period during active cancer treatment and the period following when treatment side effects may persist. Cancer treatments include surgery, chemotherapy, radiation therapy, and hormonal therapy. The guidelines address both short- and long-term side effects (generally months or even years following treatment) and treatment toxicities that affect breast cancer survivors. These graded recommendations are intended to help clinicians and patients engage in informed and meaningful dialogue with each other regardless of their final course of action.

Rating Scheme for the Strength of the Recommendations

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Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Draft guidelines were internally and externally reviewed by clinicians, researchers, patient advocates, and other stakeholders. Feedback was incorporated into the final guidelines.

Evidence Supporting the Recommendations

References Supporting the Recommendations

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Type of Evidence Supporting the Recommendations

The guidelines were developed based upon a systematic review of the published literature on randomized controlled trials investigating the use of complementary and integrative medicine during breast cancer treatment for supportive care. See Supplementary Tables 2-13 in Supplemental Appendix 2 (see the "Availability of Companion Documents" field) for a summary of the randomized trials reviewed as evidence for each therapeutic intervention considered.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of safe and effective integrative therapies as supportive care in patients treated for breast cancer to improve quality of life

Potential Harms

- An estrogenic effect from a ginseng methanolic extract has been observed in breast cancer cell lines. However, the formulation studied in the trials was a whole root product for which no long-term evidence exists regarding safety or harm.
- Mistletoe can be considered for improving quality of life in the short term, but there are limited data assessing long-term effects, interactions, and toxicities. There is some evidence of reversible hepatotoxicity at high doses of mistletoe.

Contraindications

Contraindications

Ginger should not be coadministered with the antiemetic aprepitant because of a possible negative interaction between the two agents on delayed chemotherapy-induced nausea and vomiting (CINV).

Qualifying Statements

Qualifying Statements

There are several key caveats to the recommendations presented herein. First, clinicians and patients should adopt shared decision making approaches when assessing the risk-benefit ratio for each therapy. It is important to personalize the recommendations based upon patients' values and clinical characteristics. Specific considerations that can affect the recommendation of complementary and integrative therapies include, but are not limited to: stage of disease, the overall goal of anticancer therapy (i.e., curative versus palliative); whether complementary and integrative therapies are given concurrently with anticancer therapy and if there is potential for interactions; known toxicity of specific anticancer therapy; patient performance status and patient adherence. Second, integrative approaches by definition are used alongside/in combination with

conventional medical care and should be fully communicated to all health-care providers involved in the patient's care. All modalities should be administered by qualified and experienced providers, if applicable, who have the appropriate training, licensure, and credentialing. Ongoing communication and exchange of treatment summaries among all health-care providers should take place. Third, as is the case with most therapies, responses to integrative treatments are highly variable. Patients should be monitored for efficacy and toxicity, including futility and adverse effects, and encouraged to keep symptom logs and/or use validated patient-reported outcome tools. Treatment should be stopped for unfavorable or neutral risk/benefit effects. Most of the studies testing these therapies compared the intervention of interest to standard care, so the guidelines working group cannot make claims about comparative efficacy (i.e., whether one intervention is better than another). Finally, patient preference, as well as cost, degree of invasiveness, and effort involved should be taken into account when considering treatment plans.

Limitations

As with any systematic review, there are limitations to this process. This search targeted articles focused on the use of integrative therapies during active breast cancer treatment. The guidelines working group only reviewed primary analyses of randomized controlled trials and did not analyze other systematic reviews, meta-analyses, or observational studies. In addition, the working group only included trials that were comprised of a majority of breast cancer patients, which excluded a number of high-quality trials of similar interventions among other cancer patient populations. By using search criteria that started with articles published in 1990, the working group placed a higher value on more contemporary studies because these patient populations received treatments more comparable to current breast cancer treatment regimens, while recognizing that future guidelines may include a separate set of criteria for meta-analyses and overviews. The working group took this conservative approach because no previous integrative oncology guidelines had been formulated using a highly systematic process.

A major challenge to interpreting this literature is the lack of standardization of interventions across trials using similar therapeutic approaches (e.g., natural products and mind–body therapies). Such lack of standardization can make it complicated to apply and administer the guidelines, especially for natural products. In addition, some integrative therapies are applied in a variety of settings (early versus advanced stages disease, a spectrum of symptom severity), such that the clinical criteria for using some therapies may not be straightforward. However, many of the approaches identified here are low risk (e.g., stress reduction), and the lack of standardized approaches may not greatly influence their clinical application. Future efforts focusing on increasing levels of reproducibility and standardization should be concentrated on interventions with higher risk profiles.

Though the search was detailed and clinically oriented, it may have missed some articles that addressed treatment-related effects following the treatment period. Similarly, there are a number of treatment-related side effects that are common across chemotherapy regimens and not limited to a specific cancer (e.g., febrile neutropenia, blood counts, chemotherapy-induced nausea and vomiting [CINV]). As this search was restricted to breast cancer patient populations, it may not have included the full range of legitimate trials that addressed the outcome of interest. All systematic reviews need to have a defined time period and be acknowledged as such. The field of integrative oncology is rapidly expanding and since the period of the search, a handful of trials were published on the use of yoga for mood and fatigue and quality of life, which may have upgraded the recommendations. Finally, a large number of breast cancer survivors use natural products following a diagnosis, and at this time, there is a paucity of data to inform clinical recommendations on such use.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Composition of Group That Authored the Guideline

Authors: Heather Greenlee, Lynda G. Balneaves, Linda E. Carlson, Misha Cohen, Gary Deng, Dawn Hershman, Matthew Mumber, Jane Perlmutter, Dugald Seely, Ananda Sen, Suzanna M. Zick, Debu Tripathy

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Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the [Journal of the National Cancer Institute Monographs Web site](#) .

Availability of Companion Documents

Supplemental appendices are available from the [Journal of the National Cancer Institute Monographs Web site](#) .

Patient Resources

None available

NGC Status

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